REMARKS

Preliminary Remarks

Claims 1, 4-8 and 11-14 and 20 have been amended. Claims 2-3 and 9-10 have been canceled. New claims 21-22 have been added. Claims 1-22 are now pending.

Arguments

Claims 1-20 were rejected for obviousness under U.S. Patent 5,963,967 ("Umen") in view of Microsoft Press Computer Dictionary. The Office Action states that the documents generated in the Umen system are essentially a database accessed and managed using a drug documentation system. However, the drug documentation system of Umen comprises a **regulatory submission** system in contrast to a **clinical trial database management** system (DBMS). Regulatory submission forms are used to organize and manage data **after** a clinical trial has been conducted, in order to prepare the already-collected data for submission to a regulatory agency at the conclusion of clinical trials. On the other hand, a clinical trial DBMS is a system used **during** the process of conducting clinical trials, to govern the conduct of a clinical trial, and to govern how data acquired during the trial is managed.

That the regulatory submission forms taught by Umen are different from a clinical trial DBMS is evident by the reference in Umen to a separate clinical study database (Fig. 2 reference numeral 24; col. 4, lines 56-61) in addition to the regulatory submission forms. In other words, Umen discloses **both** regulatory submission forms and a clinical trial DBMS (clinical study database). Because the forms generated by the Umen system are used to collect and present data for submission at the **conclusion** of a clinical trial, rather than for the purpose of conducting and managing data from a clinical trial, Umen teaches that the submission data must first be retrieved from a separate clinical study database that had been used to conduct the trial in the first place.

Applicant's invention, on the other hand, is directed to creating and generating a customized DBMS that is specifically designed for use **during** a clinical trial. As recited in amended claim 1, the customized DBMS "governs the management of data acquired during a clinical trial," in accordance with "clinical trial governance rules." Similar limitations are recited in amended claims 8 and 20, original claim 15 and new claim 21. As explained in the specification, for example at p. 5, lines 13-17 and p. 11, lines 16-20, clinical trial governance rules may include FDA guidelines and regulations which dictate specific methods for conducting clinical trials and managing data acquired therefrom. Applicant's customized DBMS does not merely accept post-trial data in preparation for regulatory submission, thus it is patentably distinct over the forms generated by Umen.

Applicant's invention is also patentably distinct over the clinical study database disclosed in Umen (Fig. 2 reference numeral 24; col. 4, lines 56-61). The customized DBMS of Applicant's invention is automatically generated according to a user's answers to questions in combination with a known set of clinical trial governance rules. Amended claim 1 recites "generating the customized clinical trial database management system according to the analyzing of the at least one answer and the set of clinical trial governance rules." Similar limitations are recited in amended claims 8 and 20, original claim 15 and new claim 21. Applicant's customized DMBS is thus uniquely designed to conduct a particular type of clinical trial prior to implementation of the trial. Although Umen teaches that a user may specify file names and the like within the clinical database (col. 6, line 47 – col. Col. 7, line 67), the clinical study database of Umen is pre-fabricated. It does not have a structure that is tailored to a particular clinical trial, nor is it generated in response to a user's answers to questions about the anticipated use of the clinical database. Umen simply does not teach that a clinical study database or a clinical trial database management system can be custom created in response to a user's answers to questions by

analyzing the answers and applying a set of clinical trial data management rules to them.

Applicant respectfully submits that the claims as now amended, as well as the new claims added herein, recite limitations directed to a *customized* database management system for use in *conducting* a clinical trial, which are neither taught nor suggested by the prior art.

Conclusion

Reconsideration of the above application is respectfully requested.

In view of the above, Applicant respectfully requests that a timely Notice of Allowance be issued in this case. Please charge any shortage in fees due in connection with the filing of this paper to Deposit Account 501946 and please credit any excess fees to such deposit account, referencing attorney docket number 69230-011-6806.

Respectfully submitted,

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